NOV 17 2004

510(k) SUMMARY

K042580

Submission Correspondent:	Emergo Group, Inc.
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Phone:	(727) 797-4727
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Contact:	Mr. Ian Gordon
Submission Sponsor:	Banta Healthcare Group 570 Enterprise Drive Neenah, WI 54957
Date Prepared:	September 7, 2003
Trade Name:	Tidi Brand Sterilization/CSR Wrap
Common Name:	Sterilization Wrap
Classification:	FRG, Wrap, Sterilization Class II, Regulation No. 880.6850

Description:

The Banta Healthcare Group Tidi Brand Sterilization/CSR Wrap is suitable for both medical and dental facilities as a wrapping material for sterilizing instruments and equipment. The Sterilization/CSR Wrap is made from a blue, wet formed nonwoven fabric comprised of natural wood pulp fibers bonded with a synthetic resin binder and is available in numerous sheet sizes. Sterilization/CSR Wrap is a single-use product intended for use in steam and ethylene oxide sterilization applications.

Intended Use:

Tidi brand Sterilization/CSR Wrap is suitable for both medical and dental facilities as a wrapping material for sterilizing instruments and equipment.

Available in numerous sizes, CSR wrap is a single-use product intended for use in steam and ethylene oxide sterilization applications. The wraps maintain their wrapped integrity after sterilization to maintain contents' sterility before use.

CSR Wraps can also be used for many needs that do not require sterilization, such as draping a tray and acting as a protective sheet between a surface and instruments.

Predicate Devices: The predicate device referenced in this submission is:

Ahlstrom Dexter - Dextex II Sterilization Wrap, 510(k) # K800123

Safety and Effectiveness:

The differences between the Banta Healthcare Group Tidi Brand Sterilization/CSR Wrap specifications and the predicate device specifications do not result in different performance or raise new questions regarding safety and effectiveness.

Summary and Conclusion Regarding Substantial Equivalence:

By definition, a device is substantially equivalent when the device has the same intended use and the same technological characteristics as the predicate device, or has the same intended use and different technological characteristics, but it can be demonstrated that the device is as safe and effective as the predicate device and the new device does not raise different questions regarding safety and effectiveness as compared to the predicate device.

The differences between the Banta Healthcare Group Tidi Brand Sterilization/CSR Wrap and the predicate device cited do not raise any different questions regarding safety and effectiveness. There are no differences in the technological characteristics and the associated procedures are nearly identical. The intended use is identical to the intended use of the previously cleared predicate device, and the indications are equivalent.

The device, as designed, is as safe and effective as the predicate device, and the device is determined to be substantially equivalent to the referenced predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 17 2004

Banta Healthcare Group, Limited
C/O Mr. Tamas Borsai
Responsible Third Party Official
T ÜV Rheinland of North America
12 Commerce Road
Newton, Connecticut 06470

Re: K042580
Trade/Device Name: Tidi Brand Sterilization/CSR Wrap
Regulation Number: 21 CFR 880.6850
Regulation Name: Sterilization Wrap
Regulatory Class: II
Product Code: FRG
Dated: November 3, 2004
Received: November 4, 2004

Dear Mr. Borsai

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

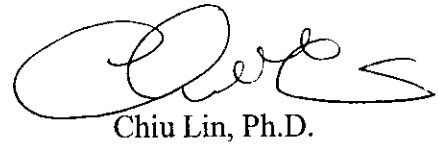
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K042580

Device Name: **Tidi Brand Sterilization/CSR Wrap**

Indications for Use:

Tidi brand Sterilization/CSR Wrap is suitable for both medical and dental facilities as a wrapping material for sterilizing instruments and equipment.

Available in numerous sizes, CSR wrap is a single-use product intended for use in steam and ethylene oxide sterilization applications. The wraps maintain their wrapped integrity after sterilization to maintain contents' sterility before use.

(PLEASE DO NOT WRITE BELOW THIS LINE -CONTINUE ON ANOTHER PAGE IF NEEDED)

510(k) Number _____

Prescription Use _____ OR Over the Counter Use X
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number K042580